

**Fluid switch Controlled Trans-cutaneously via a Magnetic Force**

5 The present application claims priority from U.S. Provisional Application Serial No. 60/430,252, filed December 2, 2002 and U.S. Provisional Application Serial No. 60/512,384, filed October 17, 2003. Both of the aforementioned provisional applications are hereby incorporated herein, in their entireties, by reference.

**Technical Field**

10 The present invention relates to implantable electronic devices and more particularly, to an implantable valve device.

**Background Art**

15 Fluid delivery systems and apparatuses are often used to provide pharmaceuticals to the body of a human or animal subject. For example, one or more liquid drugs may be delivered to the inner ear and passive or active diffusion of the liquid drug may be used to treat inner ear functions.

Such systems and apparatuses may include devices for controlling fluid flow and catheters for fluid delivery. For example, U.S. Patent No. 6,440,102 discloses an  
20 apparatus for delivering fluid materials into and out of the inner ear via the round window membrane. The apparatus includes a fluid transfer conduit having one or more passageways which may have a semi-permeable membrane associated therewith to control fluid flow. Attached to the conduit is an inflatable bladder which, when inflated, engages the internal side wall of the round window niche, thereby securing the bladder  
25 and part of the conduit within the niche. The conduit can then transfer fluids to and from the niche and the fluid-permeable round window membrane therein.

**Summary of the Invention**

30 In a first embodiment of the invention, a valve or fluid switch for a fluid delivery system is provided. The fluid delivery system is capable of being implanted in a living

subject, for example, the fluid delivery system may be part of a cochlear implant. The valve includes a fluid chamber having a fluid inlet and a fluid outlet and an internal magnet disposed within the fluid chamber. The internal magnet is moveable such that displacement of the internal magnet restricts the flow of fluid through the fluid chamber.

5 The valve may also include an external magnet disposed on the skin of the subject. The external magnet provides a magnetic field for displacing the internal magnet such that fluid flow through the fluid chamber is restricted when the internal magnet occupies a first position and fluid flow through the fluid chamber is not restricted when the internal magnet occupies a second position.

10 In accordance with related embodiments, the external magnet may be rotatable. The fluid chamber may be implanted in a subject's ear or in another part of a subject's skull. Further, the internal magnet may be formed from a biocompatible material. In accordance with other related embodiments the fluid chamber may include a first anchor and a second anchor for preventing rotation of the internal magnet. The anchors may be  
15 formed from a ferromagnetic material. Further, the fluid chamber may be formed from a non-ferromagnetic material.

In accordance with further related embodiments, the internal magnet may be spherical or cylindrical, the fluid chamber may include an anchor for securing the internal magnet in the fluid chamber and one pole of the internal magnet may include one or more  
20 grooves for permitting fluid flow through the fluid chamber when the internal magnet is secured by the anchor. The internal magnet may be coated with a non-ferromagnetic material, for example, the internal magnet may be coated with silicone. When the internal magnet is coated, the coating at one pole of the internal magnet may include one or more grooves for permitting fluid flow through the fluid chamber when the internal  
25 magnet is secured by the anchor. Alternatively, one pole of the internal magnet may include a recess for permitting fluid flow through the fluid chamber when the internal magnet is secured by the anchor. Further, one pole of the internal magnet may be replaced with or include semi-permeable material for permitting fluid flow through the chamber when the internal magnet is secured by the anchor. The anchor may be formed  
30 of a ferromagnetic material.

In accordance with other embodiments, the valve or fluid switch may further include an external indicator for checking the displacement of the internal magnet, and the external indicator may include a compass. In accordance with further embodiments, the external magnet may include a first magnet having a magnetic moment oriented in a

first direction and a second magnet having a magnetic moment oriented in a second direction such that the external magnet automatically aligns with the internal magnet. The first magnet may be cylindrical and the second magnet may be ring-shaped. Alternatively, the external magnet may be confined in a housing wherein the external magnet is capable of experiencing horizontal displacement such that it automatically aligns with the internal magnet.

In accordance with another embodiment of the invention, the valve or fluid switch for an implantable fluid delivery system may include a fluid chamber including a catheter having a fluid inlet and a fluid outlet and an internal magnet disposed within the fluid chamber. The internal magnet is moveable such that displacement of the internal magnet restricts the flow of fluid through the catheter. In a related embodiment, an external magnet may be disposed on the skin of a subject wherein the external magnet provides a magnetic field for displacing the internal magnet such that fluid flow through the catheter is restricted when the internal magnet occupies a first position and fluid flow through the catheter is not restricted when the internal magnet occupies a second position.

### **Brief Description of the Drawings**

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

Fig. 1 is graphical illustration of a fluid switch or valve in accordance with one embodiment of the present invention;

Fig. 2 is a graphical illustration of the fluid valve of Fig. 1 in an open (or ON) position;

Fig. 3 is a graphical illustration of a fluid switch or valve in a closed (or OFF) position due to an external magnet located on the skin in accordance with another embodiment of the invention;

Fig. 4 is a graphical illustration of a fluid switch or valve with a movable magnet in accordance with another embodiment of the invention;

Fig. 5 is a graphical illustration of the fluid valve of Fig. 4 in a closed (or OFF) position;

Fig. 6 is graphical illustration of a fluid switch or valve with a grooved magnet in accordance with a further embodiment of the invention;

Fig. 7 is a graphical illustration of the fluid valve of Fig. 6 in a stable closed (or OFF) position;

Fig. 8 is a graphical illustration of the fluid valve of Fig. 6 in a stable open (or ON) position;

5 Fig. 9 is a graphical illustration of a fluid switch or valve including an indicator for checking the state of the fluid switch in accordance with another embodiment of the invention;

Fig. 10 is a graphical illustration of a fluid switch or valve in which coating over one magnetic pole is recessed or replaced in accordance with a further embodiment of the  
10 invention;

Fig. 11 is a graphical illustration of a bi-stable fluid switch or valve in accordance with another embodiment of the invention;

Fig. 12 is a graphical illustration showing the effect of a fluid switching state of a fluid valve in accordance with an embodiment of the invention;

15 Fig. 13 is a graphical illustration of a magnetically activated implantable fluid switch or valve in accordance with another embodiment of the invention;

Fig. 14 is a graphical illustration of a magnetically driven fluid pump in accordance with a further embodiment of the invention;

Fig. 15 is a graphical illustration of a fluid switch or valve with includes an  
20 internal catheter in accordance with another embodiment of the invention;

Fig. 16 is a graphical illustration of the embodiment of Fig. 15 wherein flow through the internal catheter is interrupted;

Fig. 17 is graphical illustration of a fluid switch or valve having a self-aligning external magnet in accordance with a further embodiment of the invention; and

25 Fig. 18 is a graphical illustration of a fluid switch or valve having a self-aligning external magnet in accordance with another embodiment of the invention.

### **Detailed Description of Specific Embodiments**

Figs. 1 and 2 are graphical illustrations showing an ON/OFF valve (or fluid switch) used to interrupt and resume fluid flow in an implantable fluid delivery system or  
30 other fluid system. The valve **101** includes an internal but movable biocompatible magnet **102** located in a non-ferromagnetic chamber **103**. The chamber **103** includes an inlet catheter **104** and an outlet catheter **105**. The internal magnet **102** may be displaced to an open (ON) or closed (OFF) position by an external magnetic force applied at the

surface of a subject's skin **106**. In accordance with the embodiments of Figs. 1 and 2, the valve (or switching) state is controlled by the orientation of the external magnetic field.

The internal magnet **102** may be encapsulated by a gold film or other material (e.g. metal and/or polymer) to provide a biocompatible interface with the surrounding fluid or gas. The shape of the internal magnet **102** (or non-ferromagnetic case or housing **108** which contains one magnet or several magnets of any shape) may be a disk, a cube, a rectangle, a cylinder, a sphere, or any other shape.

Fig. 3 is a graphical illustration of a fluid valve in a closed (OFF) position due to an external magnet **301** located on the skin. The external magnet **301** attracts the internal magnet **102** of the fluid chamber **103** and causes closure of the fluid flow, thus bi-stable valve positions are provided. The internal magnet **102** may move, but it cannot turn and hence cannot change the axis of its magnetic momentum vector. Such an arrangement requires two anchors **106** and **107** one anchor **106** on the side facing the skin (i.e. lateral side) and a second anchor **107** on the opposite side (i.e. medial side). As shown in Figs. 1 and 2, in the absence of an external magnetic field the internal magnet **102** is dominantly attracted by that anchor **107** which is closer and the internal magnet **102** is caught in a stable position. Switching between these two stable positions can be achieved by applying an external magnetic field (such as by holding external magnet **301** over the skin). Depending on the orientation of the external magnetic field, the internal magnet **102** will either be attracted or repelled by the external field and thus will be pushed to the medial position or pulled to the lateral position. After removing the external magnet **301** (or switching off the external magnetic field) the internal magnet **102** keeps its stable position.

Figs. 4 and 5 are graphical illustrations of a fluid valve with a movable internal magnet **401** in accordance with another embodiment of the invention. In accordance with the embodiment of Fig. 4, the valve is mono-stable. Mono-stability may be achieved by a small piece of ferromagnetic material **402** (also called an anchor), which is located on the housing **408** at the side opposite to the skin (i.e. medial side). When no external field is present, the magnet is attracted by the anchor **402** and fixed in that position as shown in Fig. 5. Without the anchor **402**, the internal magnet **401** would not be held stable in its position and orientation during the absence of an external magnetic field. Such an arrangement may be exploited to interrupt or resume a fluid flow between the fluid inlet **410** and fluid outlet **411**. When an external magnetic field with correct orientation is present (such as by holding an external magnet **403** at the surface of the skin **409**, or by

generating a magnetic field with means of a current-driven electric coil) this magnetic field generates a stronger attractive force than the anchor **402**, and the internal magnet **401** is pulled towards the skin and thus can resume a fluid flow. The size of the ferromagnetic anchor **402** defines the stability of the switching state: The bigger the anchor **402**, the more robust the valve against vibration or mechanical shock and the external magnetic field needs to be stronger to attract the internal magnet.

Thus, in accordance with embodiments of the invention, the fluid valve may include two stable valve (or fluid switching) positions and two unstable valve positions. The internal magnet **401** may move along a particular axis and also can turn, thus changing the axis of its magnetic momentum vector. Such movement may be achieved with a spherical magnet as shown in Figs. 4 and 5. As described above, an anchor **402** on the medial side of the encapsulation allows fixation of the internal magnet **401** during the absence of an external magnetic field, and two stable valve (or switching) states are possible. Additionally, two unstable valve states are possible during the presence of an external magnetic field. As shown in Fig. 5, exploiting these unstable valve states (when either the north pole or the south pole of the internal magnet **401** is facing the skin **409**) requires an additional inlet **501** and outlet **502** on the side of the housing **408** which faces the skin flap **409**.

The internal magnet **401** may be free to move along a particular axis, free to turn in any direction and/or free to move and turn in a variety of manners. Similarly, the internal magnet **401** may be free to turn into any direction that is safe in the presence of strong external magnetic fields like those produced as a result of MRI (Magnetic Resonance Imaging). The internal magnet **401** may align with the external magnetic field without exerting a torque to the housing **408** of the implant, and when the internal magnet **401** is aligned it cannot demagnetize.

Fig. 6 is graphical illustration of a fluid valve (or fluid switch) with a grooved magnet in accordance with a further embodiment of the invention. In accordance with this embodiment, one pole of the internal magnet **402** (or its coating) includes grooves **601** that are made in the coating to enable fluid flow when that magnetic pole is located over the fluid inlet **410** and outlet **411**. As shown in Fig. 7, when the external magnet **403** is removed after having placed the north pole **701** of the external magnet **403** on the skin flap **409**, the north pole **703** of the internal magnet **401**, which does not have grooves, is attracted by the anchor **402**. Fluid flow between the fluid inlet **410** and fluid outlet **411** is thus interrupted by the internal magnet **401**. Fig. 8 is an illustration showing that by

removing the external magnet **403** after having placed the south pole **702** of the external magnet **403** onto the skin, the south pole **704** of the internal magnet **401**, which includes grooves **601**, is attracted to the anchor **402** and fluid may flow through the grooves **601** between the fluid inlet **410** and fluid outlet **411**.

5            Fig. 9 is a graphical illustration of a fluid valve (or fluid switch) including an indicator for checking the state of the fluid switch in accordance with another embodiment of the invention. The indicator may be a compass **901** with a needle **902** that aligns with the poles **703** and **704** of the internal magnet **401** in such a manner as to indicate the orientation of the magnetic field and thus the position of the poles. For  
10        example, the needle **902** of the compass **901** will indicate that the north pole **703** of the internal magnet **401** is closer to the skin flap **409** and that the south pole **704** (having the grooves **601**) is over the fluid inlet and outlet **410** and **411**. In accordance with this embodiment, when the internal magnet is in this position, the fluid switch is open (or ON), and fluid flow is allowed. Labeling of the compass needle **902** may also indicate  
15        the actual switching or valve state.

            Fig. 10 is a graphical illustration of a fluid valve (or fluid switch) in which coating over one magnetic pole is recessed or replaced in accordance with a further embodiment of the invention. In accordance with this embodiment, the coating over one pole of the internal magnet **401** (here the south pole **704**) is recessed or replaced with a semi-  
20        permeable material **1001**. In this manner, fluid may flow between the fluid inlet **410** and fluid outlet **1002** when this particular pole is over the fluid inlet **410** and outlet **1002**. Additionally, the embodiment of Fig. 10 may allow the implementation of open/closed (or ON/OFF) switching of fluid flow, switching between different fluid flow rates, switching of flow direction (see Fig. 13) and/or switching between different semi-  
25        permeable states (by incorporating filters or semi-permeable materials). Thus, the embodiment of Fig. 10 may be used as a fluid or gas pressure limiter to permit switching between different pressure levels.

            Fig. 11 is a graphical illustration of a bi-stable fluid valve (or fluid switch) in accordance with another embodiment of the invention. In accordance with this  
30        embodiment, bi-stable valve or switching positions are accomplished with a freely turnable internal magnet **1101** having the coating over one of its poles recessed or replaced with a semi-permeable material **1103**. The internal magnet **1101** cannot move inside its housing or containment **1108**. This allows two stable valve or switching positions, and switching can be achieved by placing a magnet over the skin for a short

time. The embodiment of Fig. 11 also permits open/closed (or ON/OFF) switching of fluid flow, switching between different flow rates, switching of flow direction and/or switching between different semi-permeable states (by incorporating filters or semi-permeable materials).

5            Fig. 12 is a graphical illustration showing the effect of a valve or switching state of a fluid valve in accordance with an embodiment of the invention. In accordance with this embodiment, a freely turnable spherical or cylindrical internal magnet **1208** is encapsulated in a hermetical non-ferromagnetic housing **1218**. The coating at poles **1210** and **1211** of the internal magnet **1208** are recessed. The anchor **1205** is placed on the lateral side (close to the skin flap **409**) or at any other place on the housing **1218** instead of at the medial side. Further, switching is performed between more than one inlet and outlet. For example, switching is performed between inlets **1203** and **1204** and outlets **1201** and **1202**. When external magnet **1206** is removed after having been placed such that the south pole **1207** of the external magnet **1206** was in contact with the skin flap  
10            **409**, the north pole **1211** of the internal magnet **1208** is closer to the skin flap **409** and recesses **1213** and **1214** permit fluid flow between fluid inlet **1203** and fluid outlet **1201**. When external magnet **1206** is removed after having been placed such that the north pole **1209** of the external magnet **1206** was in contact with the skin flap **409**, the south pole **1210** of the internal magnet **1208** is closer to the skin flap **409** and recesses **1215**, **1216**  
15            and **1217** permit fluid flow between fluid inlet **1204** and fluid outlet **1202**. A crossover/crossfeed valve may also be implemented in accordance with this embodiment.

            Fig. 13 is a graphical illustration of a magnetically activated implantable fluid valve or fluid switch in accordance with another embodiment of the invention. In accordance with this embodiment, a freely turnable spherical magnet **1301** in a non-ferromagnetic hermetic encapsulation or housing **1308** includes a bore **1302** and one-  
25            directional valve **1310**. Since the valve **1310** in the internal magnet **1301** is one directional, the orientation of the internal magnet **1301** determines whether fluid flows into the bore **1302** at the medial side **1311** of the internal magnet **1301** and out of the bore **1302** at the lateral side **1312** of the internal magnet **1301** or vice versa. When external  
30            magnet **1303** is removed after having been placed such that the south pole **1304** of the external magnet **1303** was in contact with the skin flap **409**, the north pole **1306** of the internal magnet **1301** is closer to the skin flap **409** and the internal magnet **1301** is attracted by the anchor **1309**. Fluid flows into the bore **1302** from the medial side **1311** and out of the bore **1302** at the lateral side **1312**. When external magnet **1303** is removed



after having been placed such that the north pole **1305** of the external magnet **1303** was in contact with the skin flap **409**, the south pole **1307** of the internal magnet **1301** is closer to the skin flap **409** and fluid flows into the bore **1302** from the lateral side **1312** of the internal magnet **1301** and out of the bore **1302** at the medial side **1311**.

5        Fig. 14 is a graphical illustration of a magnetically driven fluid pump in accordance with a further embodiment of the invention. In accordance with this embodiment, an ON/OFF valve (or fluid switch) and pump are used to interrupt and resume fluid flow in a fluid delivery system. The pump **1400** includes an internal magnet **1401** which is embedded in an excentrical, freely turnable and biocompatible body  
10        (“rotor”) which together with a hermetically tight membrane **1402** separates the volume inside a non-ferromagnetic chamber **1403** into two parts. The rotor **1401** is fixed stable by a small ferromagnetic part **1404** (“anchor”) during the absence of an external magnetic field. Thus, the flow valve is closed. The pump **1400** can be magnetically activated and driven by a rotating external magnetic field such as that provided by external rotating  
15        magnet **1405** (or an arrangement of solenoids). In this manner, fluid flow direction and the fluid flow rate may be controlled.

      Fig. 15 is a graphical illustration showing a fluid valve or fluid switch with includes an internal catheter in accordance with another embodiment of the invention. Here again, the valve **1501** includes an internal but movable biocompatible magnet **1502**  
20        located in a non-ferromagnetic chamber **1503**. The chamber **1503** includes an internal catheter **1509** having an inlet **1504** and an outlet **1505**. The internal magnet **1502** may be displaced so as to create an open (ON) position, wherein flow through the internal catheter **1509** is not interrupted or a closed (OFF) position wherein flow through the internal catheter **1509** is interrupted as shown in Fig. 16. As in the embodiment of Fig. 1,  
25        the internal magnet **1502** may be encapsulated by a gold film or other material (e.g. metal and/or polymer) to provide a biocompatible interface with the surrounding fluid or gas. The shape of the internal magnet **1502** (or non-ferromagnetic case or housing **1503** which contains one magnet or several magnets of any shape) may be a disk, a cube, a rectangle, a cylinder, a sphere, or any other shape.

30        Fig. 16 is a graphical illustration of a fluid valve or fluid switch in a closed (OFF) position due to an external magnet **1601** located on the skin. The external magnet **1601** attracts the internal magnet **1502** of the fluid chamber **1503**. Consequently, the internal magnet **1502** squeezes the internal catheter **1509** and fluid flow through the internal catheter **1509** is interrupted.

Fig. 17 is graphical illustration of a fluid valve or fluid switch having a self-aligning external magnet in accordance with a further embodiment of the invention. In accordance with this embodiment, the fluid valve includes an external magnet **1701** having a quadru-polar magnetic momentum. This is accomplished in that the external magnet **1701** includes an arrangement of two or more magnets with their magnetic moments oriented in different direction. Such an arrangement provides improved self-aligning (or self-centering) properties of external magnet **1701** over an implanted magnet **1702**. In accordance with the arrangement shown in Fig. 17, the external magnet **1701** includes a cylindrical magnet **1703** and a ring-shaped magnet **1705** with opposite magnetization.

Fig. 18 is a graphical illustration of a fluid valve or fluid switch having a self-aligning external magnet in accordance with another embodiment of the invention. In accordance with the embodiment of Fig. 18, the fluid valve is provided with an external magnet **1801** that is confined in a box **1803** housing such that the external magnet **1801** is mechanically free to move horizontally (i.e., normal to its axis of magnetization). In this manner, precise alignment of the external magnet with an implanted magnet is permitted, even if the box or housing **1803** is not exactly placed over the implanted magnet.

Embodiments of the invention may be used for systems or applications other than human drug delivery. For example, the valves or fluid switches of the invention may be applied in biomedical engineering in general, automotive, domestic technique or other industries. Similarly, the embodiments of the invention may be used to magnetically control the flow of liquids and gases. Further, the external magnetic field can originate from an electro-magnet (current-driven coil) instead of a permanent magnet. Valves or fluid switches as described above may further be used to close a pump system while refilling a fluid reservoir and such valves or fluid switches may be used with an osmotic pump.

While the invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modification. This application is intended to cover any variation, uses, or adaptations of the invention and including such departures from the present disclosure as come within known or customary practice in the art to which invention pertains.

01941/00172 282901.1